IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY and EDEN BIODESIGN, LLC.	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-1727 (RGA)
AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., ALKEM LABORATORIES LIMITED, HETERO LABS LIMITED, HETERO USA INC., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED and ZYDUS PHARMACEUTICALS (USA) INC.,	)	
Defendants.	)	

JOINT LETTER BRIEF TO THE HONORABLE JUDGE RICHARD G. ANDREWS REGARDING PROTECTIVE ORDER DISPUTE

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Dear Judge Andrews:

The parties submit this joint letter regarding a disputed provision in the parties' proposed protective order (Ex. A ¶ 12). The parties' respective positions regarding their competing proposals for that provision are set forth below.

I. Plaintiffs' Position

This is a Hatch-Waxman case arising from the efforts of six companies to market generic versions of Plaintiffs' Viberzi® drug product. In a case like this, involving multiple defendants and related issues pertaining to validity and infringement, Plaintiffs propose that the protective order allow for the limited disclosure of any individual defendant's confidential information to the outside counsel and experts for other defendants. Ex. A ¶ 12. Defendants' proposal seeks to prevent any such disclosure, except for at hearings and trial, by requiring Plaintiffs to obtain written approval from the individual defendant prior to any such disclosure.

An individual defendant's confidential information may be relevant to positions taken by other defendants. For example, the Federal Circuit has routinely relied on third-party information when considering objective indicia of non-obviousness, including the failure of others, long-felt need, copying, commercial success, and industry praise. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1081–82 (Fed. Cir. 2012) (third-party's failure supported a finding of non-obviousness). For reasons of fairness and efficiency, Plaintiffs should be able to use one defendant's confidential information, if necessary, to rebut positions being taken by other defendants, and Plaintiffs' ability to use such evidence should not be conditioned on obtaining any individual defendant's consent on a case-by-case basis. Indeed, D. Del. LR 26.2 provides for outside counsel access even in the absence of a protective order, and Defendants' proposal unnecessarily contradicts that rule.

Given the size of this case, Defendants' proposal would result in unnecessary administrative burdens on both Plaintiffs and the Court and would also likely lead to needless disputes. At the very least, Defendants' proposal would impede discovery and depositions by, for example, requiring individual expert reports and depositions for each defendant and a multiplication of discovery disputes and motion practice. Conversely, Plaintiffs' proposal would, as other judges in this District have recognized, aid in the orderly administration and handling of the case. *Pharmacyclics LLC v. Fresenius Kabi USA, LLC*, No. 18-192-CFC, Oral Order (D. Del. Oct. 18, 2018) (Ex. B) (adopting plaintiffs' proposed cross-use provision for the protective order because, among other reasons, defendants' contrary proposal "would lead to significant disruptions in discovery, depositions, and court proceedings and would impose an undue burden on the Court."); *H. Lundbeck A/S v. Apotex, Inc.*, No. 18-88-LPS, Oral Order (D. Del. Sept. 13, 2018) (Ex. C) (rejecting defendants' proposal precluding cross-use without prior consent because the "proposal . . . risks imposing an undue burden on the Court (independent of the burden it imposes on Plaintiffs)"); *see also Shire, LLC v. CorePharma LLC*, No. 14-5694-JS, tr. at 28:24-29:2 (D.N.J. May 18, 2015) (Ex. D) ("If the Court adopts Par's suggestion, the Court believes that it would create intractable management problems dealing with depositions, expert reports, the Markman hearing, et cetera.").

Plaintiffs' proposal, if adopted, will not result in any prejudice to Defendants. Plaintiffs' provision would confine the cross-disclosure of Defendants' confidential information to outside counsel and experts bound by the protective order and subject to the jurisdiction of this Court.[1] These individuals, by definition, cannot be competitive decision-makers, and there is no serious risk of disclosure or misuse of confidential information *See Pharmacyclics*, No. 18-192-CFC, tr. at 20:18-21:19 (D. Del. Oct. 17, 2018) (Ex. E) (highlighting that those bound by a protective order are assumed to be willing and able to comply with it). Defendants have not identified any real risk, and it is their burden to show that the limited disclosure Plaintiffs have proposed should be prohibited. *See* Fed. R. Civ. P. 26(c); *In re Deutsche Bank Trust Corp.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010) ("A party seeking a protective order carries the burden of showing good cause."). Moreover, Defendants have availed themselves of the Hatch-Waxman statute to seek to bring their generic drugs to market and, accordingly, knew that litigation involving the limited disclosure of their respective confidential information would ensue. Indeed, at least some defendants have previously agreed, in other cases, to the limited type of cross-disclosure Plaintiffs seek. *See*, *e.g.*, *Amgen Inc. v. Aurobindo Pharma Ltd.*, No. 16-853-GMS, D.I. 108 at 10, ¶ 13 (D. Del. May 4, 2017) (Ex. F). In contrast, none of the cases cited by Defendants addressed the compromise proposal set forth by Plaintiffs here, which tracks D. Del. LR 26.2. Finally, under the terms of the protective order, Plaintiffs are entrusting their confidential information to the same individuals Defendants seek to block from viewing their confidential information. Defendants have provided no rationale for why it is safe to share Plaintiffs' information, but dangerous to share their own.

II. Defendants' Position

A. There is good cause to implement Defendants' proposal

No party to this litigation should be allowed to disclose one Defendant's highly sensitive technical and financial information ("Confidential information") to another Defendant, without permission. Paragraph 12 of the Protective Order ("PO") is necessary to protect confidential details of each Defendant's proposed ANDA product and to ensure Defendant has control over disclosure of their own Confidential information. Defendants' proposal for paragraph 12 further properly protects Defendants' business interests, and correctly reflects the state of the law that specifically recognizes that this type of Confidential information requires protection.

i. Defendants' proposal is efficient and prevents potential prejudice

Defendants' proposal for paragraph 12 is an efficient and even-handed method of controlling disclosure of a Defendant's Confidential information. *See Supernus Pharms., Inc. v. Actavis, Inc.*, No. 14-cv-06102, D.I. 77 at ¶ 2 (D.N.J. Sept. 23, 2015) (recognizing "efficiency in permitting each Defendant control over the disclosure of its confidential information to its direct competitors without unduly interfering with Plaintiffs ability to prosecute its case"). Defendants' proposal would not disrupt discovery, depositions, or court proceedings or present undue burdens on Plaintiffs because it allows for disclosure in certain circumstances. In fact, Plaintiffs refer to the supposed

[1] Plaintiffs' proposal would not, as Defendants suggest, allow any defendant to share another's confidential information with its in-house designees without the consent of that defendant.

burden under Defendants' proposal as "administrative." Contrary to Plaintiffs' suggestion, there is nothing in the Hatch-Waxman Act that requires or implies forced disclosure of a Defendant's Confidential information. Furthermore, Plaintiffs' reliance on *In re Cyclobenzaprine* misses the point because the parties are not disputing reliance on third-party information to establish secondary considerations.

Defendants' proposal lessens the risk that any Defendant's Confidential information can be accessed by direct competitors, *i.e*. the other Defendants. The content and status of drug applications are part of Defendants' highly guarded research and business strategy that they do not share with their competitors. While Defendants have and will collectively address a set of common, nonconfidential issues, each Defendant has different bases for noninfringement.

Plaintiffs proposal would unduly prejudice Defendants. The PO permits disclosure of all Confidential information to designated in-house counsel or representatives. *See* PO at ¶ 14. Under Plaintiffs' proposal, if *Plaintiffs* disclose the Confidential information of one Defendant to another, any designated in-house counsel or representative would be free to review it. Such a disclosure would present an actual and substantial harm to the producing party because the information could be used to gain a business or market advantage. *See American Standard Inc. v. Pfizer Inc*., 828 F.2d 734, 741 (Fed. Cir. 1987) (affirming that a defendant would be harmed by disclosure of a defendant's confidential information to competitors who were also parties to the litigation.) While designated in-house counsel and representatives will have executed a signed Undertaking, "[i]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so." *T-JAT Systems 2006 Ltd. v. Expedia, Inc. (DE)*, Civil Action No. 16-581-RGA (D. Del. Oct. 19, 2018) (D.I. 87 at 5) (Ex. 1).

ii. Defendants' proposal accords with similar authority

Defendants' proposal for paragraph 12 is supported by prior decisions from this Court and the District Court of New Jersey. *See, e.g., AstraZeneca LP v. Sigmapharm Labs., LLC*, C.A. No. 15-01000-RGA (D. Del. April 26, 2016) (D.I. 71 at ¶ 16) ("absent written consent from the producing party, Plaintiffs may not produce or otherwise make available Defendant's Protected Information to any other Defendant") (Ex. 2); *Astellas v. Actavis*, No. 16-905-SLR-CJB (D. Del. July 20, 2017) (D.I. 65 at ¶ 3) ("In balancing here between the competing interests of (1) litigation-related efficiency and (2) protecting the parties' confidential information, the Court errs on the side of the latter.") (Ex. 3); *Novartis Pharms. Corp. v. Apotex Inc., et al*., C.A. No. 18-1038-LPS (D. Del. Oct. 16, 2018) (D.I. 44 at 37:12-15) ("I'm more comfortable with something along the lines of the first sentence, the 'without prior written approval, no party may disclose the protected information of any defendant to another defendant.'") (Ex. 4); *In re Fetzima*, C.A. No. 17-10230 (ES) (SCM) (D.N.J. May 21, 2018) (D.I. 67 and 82 at ¶ 15) (adopting a defendant's proposal to exclude co-defendant outside counsel attendance at depositions where one defendant's confidential information would be used or elicited) (Exs. 5 and 6).

Respectfully,

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

cc: Clerk of the Court (by CM/ECF)
All Counsel of Record (by CM/ECF and email)